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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,885	03/22/2002	Thomas Fahrig	Le A 33 914	5212

7590 10/09/2003
Jeffrey M Greenman
Vice President, Patents and Licensing
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EXAMINER

FORD, JOHN M

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 10/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/088885

Applicant(s)

Fahrig et al

Examiner

Jim Ford

Group Art Unit

1624

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1 - 8 is/are pending in the application.
Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1 - 8 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claim(s) 1 - 8 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other _____

Office Action Summary

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The claims in the application are claims 1—8.

The variation in TXA (page 101); B (page 105); R7 (page 108) creates a molecule that cannot be searched.

There are too many variables.

Applicants need to elect a value of TXA and B and R7 to begin to have a molecule that could be recognized and searched.

Claim 5 is a good start, if R7 were fixed, as in claim 4, but we need to know what the whole molecule is. It cannot be understood, what, exactly, is being claimed in claim 5; the claim appears incomplete.

Election of the subject matter of claim 4 would be helpful, so we could have a starting point of constructing a mutually arrived at genus that could be searched.

This application contains claims directed to patentably distinct species.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Claim 1 is generic to a plurality of patentably distinct species. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even if this requirement is traversed. See 37 CFR 1.143.

Claims 1—4 violate 35 U.S.C. 101 and 35 U.S.C. 112, since they are drafted in terms of use. See *Clinical Product vs. Brenner*, 255 F. Supp. 151; 149 USPQ 475 (D.C. District Columbia 1966).

Claim 5 is incomplete as it mentions formula I' but such a formula is not in claim 5. Formula I' is in claim 2, but claim 5 is not dependent on claim 2. (35 U.S.C. 112, 2nd paragraph.)

Claim 6 is rejected under 35 U.S.C. 112 as "at least" is open to the inclusion of unknown. One or more is suggested.

Claim 7 is rejected under 35 U.S.C. 103, as the preparation of a composition by mixing is well known since the time of Alchemists working in Caves. See *Remington Practice of Pharmacy*, or the art of Record.

Claim 8 is not "statutory", as it is claimed in terms of "use", and is recited as a "medicament". The claim never says what real world disease is being treated. A "medicament" is not statutory. The claim has to be expressed as a Pharmaceutical composition, or a method of treating a real world disease.

The recent utility guidelines set by PTO require applicant to meet the requirements as stated in *Brenner v. Manson* in, 148 USPQ 689, which requires that utility be developed to a point where "specific benefits exist in currently available form". Similar is the "immediate benefit to the public" standard that

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Nelson v. Bowler, 206 USPQ 880 refers to. The standard set forth in the concurring opinion of In re Hartop, 135 USPQ 419 is "whether the invention has been brought to such perfection as to be capable of practice employment". This language is echoed in Bindra vs. Kelly, 206 USPQ 570.

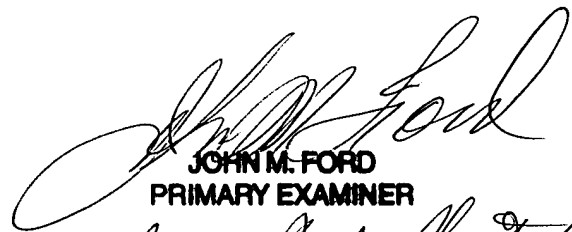
The PTO has amended the guidelines to clarify "specific utility". The court focused on the fact that the applicants failed identify a "specific utility" in Brenner v. Manson.

This requirement of one specific utility is consistent with Unity of Invention Practice in International Application s and National Phase Applications under 35 U.S.C. 371, and PCT Rule 13.2 for PCT applications.

Therefore, applicants should direct the method claims to a "specific utility".

J. M. Ford:jmr

October 7, 2003


JOHN M. FORD
PRIMARY EXAMINER
Group A Unit 1624